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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,144	11/25/2003	Robert J. Hariri	9516-495-999	6313

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,144	HARIRI, ROBERT J.	
	Examiner	Art Unit	
	Laura McGillem	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 3/28/2007.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1,3,5-6,8,12-13,15-18,20-23,31,32,34-37 and 50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,3,5,6,8,12,13,15-18,20-23,31,32,34-37 and 50 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

It is noted that claims 1, 18, 31, 34 and 50 have been amended in the response filed 4/16/2007. Claims 1, 3, 5-6, 8, 12-13, 15-18, 20-23, 31-32, 34-37 and 50 are under examination.

Double Patenting

Claims 1, 3, 5-6 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 10 and 13-14 of copending Application No. 10/366,671 in view of Erices et al (Br. J. Haematol., 2000 Vol. 109, No.1, abstract). The claims are not patentably distinct from one another because the product of the instant claims is an obvious variation of the composition of copending Application No. 10/366,671.

This is a provisional obviousness-type double patenting rejection. Applicant requests that the rejection be held in abeyance until one set of claims is deemed to be in condition for allowance.

This rejection is being maintained for reasons of record in the previous Office Action, mailed 12/28/2006 but will be held in abeyance until one set of claims is deemed to be in condition for allowance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5-6, 8, 12-13, 15-18, 20-23, 31-32, 34-37 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention.

Independent claims 1, 18, 31, 34 and 50 have been amended to recite a cytotherapeutic unit comprising a plurality of cells "wherein said plurality of potent cells comprises $CD34^-OCT\text{-}4^+$ cells that have been isolated from postpartum placental perfusate". The claimed cytotherapeutic unit also comprises at least about one hundred $CD34^+$ cells or at least about one hundred $CD8^+$ cells within the plurality of cells. The instant disclosure does not describe or support the specific combination of a cytotherapeutic unit comprising a plurality of cells wherein the plurality of cells comprises $CD34^-OCT\text{-}4^+$ cells that have been isolated from postpartum placental perfusate and also at least about one hundred $CD34^+$ cells or at least about one

hundred CD8+ cells. The specification discloses broad embodiments of the claimed cytotherapeutic unit.

For example paragraph 0011 discloses:

"The identities of the potent cells preferably reflect the presence or absence of at least one antigenic determinant on the cells. In some embodiments, the cytotherapeutic unit comprises at least some potent cells exhibiting CD34, CD8, CD10, OCT4, CD38, CXCR4, or CD117, for example. In some embodiments some portion of the cells may also exhibit CD33. In some preferred embodiments, the cytotherapeutic unit comprises cells that lack specific antigenic determinants. In other embodiments, at least one identified potent cell that is derived from a source is specifically excluded or removed from the cellular preparation. "

Further paragraphs 0012 and 0023 disclose:

"In one embodiment of the invention, some or all cells may be characterized by the presence of one or more of the following cell surface markers: $CD10^+$, $CD29^+$, $CD34^-$, $CD38^-$, $CD44^+$, $CD45^-$, $CD54^+$, $CD90^+$, $SH2^+$, $SH3^+$, $SH4^+$, $SSEA3^-$, $SSEA4^-$, $OCT\text{-}4^+$, and $ABC\text{-}p^+$."

At paragraph 0029, the specification contemplates a cytotherapeutic unit wherein at least one cell type is excluded and suggests that in some embodiments all CD34 positive cells will be excluded or all CD8 positive cells will be excluded. These are broad disclosures of a cytotherapeutic unit comprising at least some potent cells exhibiting CD34, CD8, CD10, OCT4, CD38, CXCR4, or CD117, for example and some embodiments that lack specific antigenic determinants. This does not provide sufficient description of the claimed unit comprising a plurality of cells with the limitation that it comprises $CD34^+$ cells and the specific combination of $CD34^-$ $OCT\text{-}4^+$ cells. This disclosure does not sufficiently describe an embodiment of the unit comprising are $CD34^-$ $OCT\text{-}4^+$ and some are $CD8^+$. The cytotherapeutic unit as claims is not disclosed or contemplated in the specification or the examples given. Example 1

describes a unit that contains no less than one percent of $CD34^+$ cells and no less than 2.5 percent of $CD8^+$ cells. Example 2 describes a unit that contains no less than one percent of $CD34^+$ cells at a ratio of 2:1 as $CD34^+/CD33^+$: $CD34^+$ /$CD33^-$. Example 3 describes a unit that contains no less than 0.25 percent of $CD34^+$ /$CD38^-$ cells and no less than 0.5 percent depletion of $CD8^+$ cells. Further, the disclosure does not sufficiently describe a specific cytotherapeutic unit in which the $CD34^-$ $OCT\text{-}4^+$ cells are isolated from postpartum placenta perfusate

The specification does not describe or exemplify the claimed invention so that skilled artisan would be able to envision the specific combination of CD34-$OCT\text{-}4^+$ cells and at least about one hundred $CD34^+$ cells, or $CD34^-OCT\text{-}4^+$ cells and at least about one hundred CD8+ cells from the instant specification. Therefore the claimed invention as written constitutes new matter.

Claim Rejections - 35 USC § 102

Applicant's arguments, see REMARKS (page 5-6), filed 3/28/2007, with respect to claims 1, 3, 5-6, 8, 15-18, 20-23, 31-32, 34, 36-37 and 50 have been fully considered and are persuasive. Claims 1, 18, 31, 34 and 50 have been amended to specify that the recited cytotherapeutic units comprise potent CD34-$OCT\text{-}4^+$ cells that have been isolated from placental perfusate. Fasouliotis does not appear to teach the separation of potent $CD34^-OCT\text{-}4^+$ cells from perfusate. The rejection of Claims 1, 3, 5-6, 8, 15-18, 20-23, 31-32, 34, 36-37 and 50 under 35 U.S.C. 102(b) as being anticipated by Fasouliotis et al has been withdrawn.

Claim Rejections - 35 USC § 103

Applicant's arguments, see REMARKS (page 6-7), filed 3/28/2007, with respect to claims 1, 3, 5-6, 8, 12, 15-18, 20-23, 31-32, 34- 37 and 50 have been fully considered and are persuasive. Claims 1, 18, 31, 34 and 50 have been amended to specify that the recited cytotherapeutic units comprise potent CD34-OCT-4$^+$ cells that have been isolated from placental perfusate. Pykett does not teach or suggest a cytotherapeutic unit that comprises potent CD34$^-$OCT-4$^+$ cells. Fasouliotis also does not teach or suggest such cells, and therefore does not remedy the deficiencies of Pykett. The rejection of Claims 1, 3, 5-6, 8, 12, 15-18, 20-23, 31-32, 34- 37 and 50 under 35 U.S.C. 103(a) as being unpatentable over Pykett et al in view of Fasouliotis et al has been withdrawn.

Applicant's arguments, see REMARKS (page 7-8), filed 3/28/2007, with respect to claims 1, 3, 5-6, 8, 12, 15-18, 20-23, 31-32, 34- 37 and 50 have been fully considered and are persuasive. Pykett does not teach or suggest a cytotherapeutic unit that comprises potent CD34$^-$OCT-4$^+$ cells. Wang does not teach or suggest potent CD34-OCT-4+ cells, or cytotherapeutic units comprising such cells. The rejection of claims 1, 3, 5-6, 8, 12, 15-18, 20-23, 31-32, 34- 37 and 50 under 35 U.S.C. 103(a) as being unpatentable over Pykett et al in view of Wang et al (Blood, 2001 Vol. 98 (No. 11 Part 1) page 193 (abstract only)) has been withdrawn.

Applicant's arguments, see REMARKS (page 8), filed 3/28/2007, with respect to claims 1-6, 8, 15-18, 20-23, 31-32, 34-35, 37 and 50 have been fully considered and are persuasive. Claims 1, 18, 31, 34 and 50 have been amended to specify that the recited cytotherapeutic units comprise potent CD34-OCT-4$^+$ cells that have been isolated from placental perfusate. Johnson does not appear to teach such cells. Fasouliotis also does not appear to teach or suggest such cells. The rejection of claims 1-6, 8, 15-18, 20-23, 31-32, 34-35, 37 and 50 under 35 U.S.C. 103(a) as being unpatentable over Johnson et al in view of Fasouliotis et al has been withdrawn.

Applicant's arguments, see REMARKS (page 9), filed 3/28/2007, with respect to claims 1 and 12-13 have been fully considered and are persuasive. Fasouliotis does not appear to teach or suggest potent CD34-OCT-4$^+$ cells that have been isolated from placental perfusate. Ende does not appear to teach or suggest such cells. The rejection of claims 1 and 12-13 under 35 U.S.C. 103(a) as being unpatentable over Fasouliotis et al in view of Ende et al has been withdrawn.

Applicant's arguments, see REMARKS (page 9-10), filed 3/28/2007, with respect to claims 1, 3, 5-6, 8, 12, 15-18, 20-23, 31-32, 34- 37 and 50 have been fully considered and are persuasive. Johnson does not appear to teach or suggest CD34-OCT-4$^+$ cells that have been isolated from placental perfusate, and does not teach or suggest a cytotherapeutic unit comprising such cells. Likewise, Wang does not appear to teach or suggest potent CD34-OCT-4$^+$ cells, or cytotherapeutic units comprising such cells. The

rejection of claims 1, 3, 5-6, 8, 12, 15-18, 20-23, 31-32, 34- 37 and 50 under 35 U.S.C. 103(a) as being unpatentable over Johnson et al in view of Wang et al has been withdrawn.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura McGillem, PhD
Examiner
6/21/2007

CELINE QIAN, PH.D.
PRIMARY EXAMINER